

### **REMARKS/ARGUMENTS**

Claims 3, 15, and 22 were rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. Claims 1, 2, 7, 8, 14-19, 22, and 24-28 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,704,945 to Wagner et al. Additionally, new rejections were made of Claims 1-28 as being anticipated by WO 99/08621 to Zahedi.

#### **Response to Rejections**

Applicant respectfully submits that the Office Action as a whole reflects unrealistically broad interpretations of terms in the claims. Nevertheless, Applicant has amended the independent claims to further distinguish them from the cited references. In addition, Claims 3 and 15 have been amended to address the 35 U.S.C. 112, second paragraph objections. Claim 3 now recites "said valve" as being the "main valve" rather than reciting "said valve" as comprising the "main valve".

With regard to Claim 15, the phrase pointed out by the Examiner has been deleted.

With regard to Claim 22, Applicant respectfully submits that "the knee axis of rotation" in line 6 of Claim 22 has an antecedent in line 2. Nevertheless, this has been clarified by amending line 2.

The Examiner has maintained the position that Claim 1 is anticipated by Wagner et al. Applicant submits that such a position overlooks the fact that, in this art, "knee stabilisation" refers to preventing collapse of the knee during the *stance* phase and that to be "weight-responsive" the valve control arrangement of the present invention operates during the stance phase when the amputee's weight is applied to the prosthetic mechanism. The adjustable check valves of Wagner in Figure 7 are for controlling the *swing* phase, not the stance phase (see column 3, lines 4 to 6 and column 4, lines 21ff).

Furthermore, in attempting to read Claim 1 onto Wagner, the Examiner adopts unreasonable or incorrect interpretations of the claim. For example, in the "Response to Arguments" on page 2 of the Office Action, it is asserted that the ball 34 in Wagner is moveable towards its open position in response to fluid pressure in the passage because "the open position would be in the direction away from the valve seat and fluid pressure upstream causes the ball to move in this direction". This is unreasonable. Applicant fails to see how moving the ball away from one seat so that it forms a flow restriction with the *other* seat can reasonably be described as moving towards an "open" position in which fluid can flow through the passage to allow joint flexion (as opposed to at least restricting such fluid flow), as required by Claim 1.

The Examiner goes on to assert that "broadly interpreted" the springs and pins in Wagner Figure 7 are weight-responsive. With all due respect, they are not. In use of the Wagner prosthesis, application of the amputee's weight does not cause the springs and pins in Figure 7 to resist movement of the ball 34 in the direction of the open position. Nothing except the ball 34 itself acts on the pins and springs.

However, to further distinguish Claim 1 from Wagner, Applicant has amended the claim to recite a knee-stabilizing device for resisting joint flexion "during a stance phase of the walking gait cycle" (see page 11, lines 29 to 31, for example, for support). The stabilizing device is also recited as including "a stance phase" weight-responsive valve control arrangement "which, in use, operates in response to patient loading" to at least resist movement of the valve member in the direction of its open position "thereby to cause the mechanism to resist joint flexion during the stance phase".

The check valves 31, 32 of Wagner's Figure 6 and Figure 7 have no practical effect during the stance phase, i.e., when joint flexion is controlled by the valve plunger 23 (see Wagner, Figures 4 and 5). Check valves 31 and 32 are only for *swing* phase control. The stance phase control system of Wagner, i.e., valve plunger 23 and associated components, suffers from the disadvantage described on page 1 of the description in that significant movement is required to close the valve formed by the plunger 23 in its housing, thereby creating a period of instability

until the knee is locked. In the claimed invention, by requiring the valve member to be moveable towards its open position in response to fluid pressure caused by knee flexion, and resisting such movement when the knee is loaded by the amputee's weight, the delay of the prior art mechanism is avoided.

Claim 1 is, therefore, novel and non-obvious over Wagner.

Claim 17 has been amended similarly to Claim 1 and is novel and non-obvious for similar reasons. The same applies to Claim 22.

With regard to Claim 27, Applicant can see no basis for the Examiner's contention that Wagner in Figure 7 anticipates this claim. For example, Applicant can see no valve member that is resiliently biased towards the closed position in Wagner Figures 6 and 7. The ball 34 is not resiliently biased towards a closed position. The ball 34 also does not have a "piston part", let alone one that is located in a bore opening "into the cavity on an opposite side of the cavity from" an outlet port. The Examiner has not indicated, nor can Applicant see, where in Wagner's Figure 7 there are different effective sealing areas as required by Claim 27, nor any circumstance in which ball 34 is caused to move away from a closed position in the event of pressure in the cavity caused by an excess flexion moment being applied to the joint mechanism.

Nevertheless, Applicant has amended Claim 27 to add stance phase restrictions as in the other independent claims, to add to the distinction of the claim from Wagner. It is respectfully submitted that amended Claim 27 is patentable over Wagner.

The Office Action cited a new reference, Zahedi et al. (U.S. 6,517,585) which is one of Applicant's earlier patents. The Office Action applied a cursory and incorrect analysis in respect of present Claim 1. The Office Action asserted that the "valve" and "valve member" of Claim 1 are one of 18G, 18N, or 18P in Zahedi. None of these elements satisfies the requirements of Claim 1. 18G closes on flexion and 18P is independently controlled (by solenoid 18Q), so neither of these components meets the claim limitation. In fact, the only valve member in Figure 1 of Zahedi that has an open position in which fluid can flow through the passage to allow joint

flexion and is moveable towards its open position in response to fluid pressure is the ball of non-return valve 18N. However, valve 18N does not have a stabilizing position in which it restricts fluid flow through its associated passage to prevent joint flexion, nor is there a weight-responsive valve control arrangement resisting movement of the ball of valve 18N towards its open position in which fluid can flow through the passage to allow joint flexion.

Claims 17 and 22 are similarly distinguished from Zahedi.

In rejecting Claim 27, the Office Action relied on the pneumatic part of the mechanism of Zahedi in Figure 1, justifying this by asserting that “hydraulic” can include gases. This is an unreasonable interpretation of “hydraulic”, the commonly accepted definition of which is “of or relating to water or other liquid in motion” (see Webster’s Third New International Dictionary). No person of ordinary skill in the art would understand “hydraulic” mechanisms to include pneumatic mechanisms.

Furthermore, as apparent from the way the spring (not numbered) is arranged with respect to the valve member 18H in Zahedi, the valve member 18H is biased towards its *open* position, not its closed position as Claim 27 requires. Even more importantly, opening and closing of Zahedi’s valve 18H is governed solely by the stepper motor 20. Valve 18H has no excess-pressure opening as claimed in the last three lines of Claim 27 (“the valve member is caused to move away from its closed position in the event of pressure in the cavity caused by an excessive flexion moment applied to the joint mechanism during the stance phase”), not least because valve 18H is pneumatic and air, unlike hydraulic oil, is easily compressible.

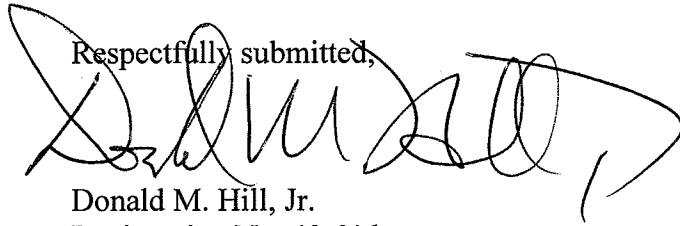
Accordingly all of the claims as presented are patentable over Zahedi.

### Conclusion

Based on the above amendments and remarks, Applicant submits the application is in condition for allowance.

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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

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